510(k) Summary

Zeus Scientific VZV IgM ELISA Test System

JUL - 5 2007

510(k) 070317

As required by 21 CFR 807.92, the following 510(k) summary is provided:

1 Submitter Information

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Establishment Registration Number: 224236

2 Device Information

Proprietary Name: Zeus Scientific Varicella-Zoster (VZV) IgM ELISA Test Kit
Classification Name: Varicella-zoster Virus Serological reagents
Class: Class II
CFR: 866.39
Product Code: LFY

3 Predicate Device Information

Manufacturer: Trinity Biotech
Name: Captia VZV IgM ELISA Test Kit
Methodology: ELISA
510(k) Number: Unknown

4 Device Description

The Zeus Scientific VZV IgM ELISA Test System is an enzyme linked immunosorbent assay intended for the qualitative detection of distict IgM antibody to the Varicella-zoster virus.

The test is designed to detect IgM antibody using inactivated VZV antigen: strain, Ellen.

5 Intended Use

The Zeus Scientific VZV IgM ELISA Test System is intended for the qualitative detection of IgM antibody to Varicella-Zoster virus in human serum as an aid in diagnosis of primary infection or reactivation.

The assay performance in detecting antibodies to VZV in individuals Vaccinated with the FDA licensed VZV vaccine is unknown. The user of this Assay is responsible for establishing the performance characteristics with VZV vaccinated individuals. The assay performance in detecting antibodies to VZV antibodies to VZV in cord blood and neonates has not been established.

6 Summary of Technological Characteristics

The Zeus Scientific VZV IgM ELISA Test System is designed to detect IgM class antibodies in human sera to Varicella-zoster virus. Wells of plastic microwell strips are sensitized by passive absorption with VZV antigen. The test procedure involves three incubation steps:

Test sera are diluted with the Sample Diluent provided. The Sample Diluent contains anti-human IgG that is intended to bind IgG and Rheumatoid factor to prevent non-specific binding to the immobilized antigen. During sample incubation, any antigen specific IgM antibody in the sample will bind to the immobilized antigen. The plate is washed to remove unbound antibody and other serum components.

Peroxidase conjugated goat anti-human (μ chain specific) is added to the wells and the plate is incubated. The conjugate will react with IgM antibody immobilized in the solid phase I, step 1.

The microwells containing immobilized peroxidase conjugate are incubated with peroxidase substrate solution. Hydrolysis of the substrate by peroxidase produces a color change. After a period of time, the reaction is stopped and the color intensity of the solution is measured photometrically. The color intensity of the solution depends upon the antibody concentration in the original test sample.

7 Performance Data

Non-Clinical

Establishment and Verification of Cut-off

The cut-off corresponds roughly to the mean plus (X) times the Standard Deviation of a negative population, X being the multiplication factor necessary to optimize the assay results.

25 known negative samples, confirmed by a commercially distributed ELISA assay were tested to establish the cut-off. Additionally, a minimum of 5 known positive samples, also confirmed by a commercially distributed ELISA assay were tested. The results of the known positive samples were ascertained to exceed the theoretical cut-off as well as the negative samples were ascertained to fall below the theoretical cut-off.

Linearity

Four positive samples were tested neat and with two-fold serial dilutions using the Zeus Scientific VZV IgM ELISA Test System. Results verify the linearity of the assay cut-off.

Limits of Detection

Four strongly positive samples were serially diluted and tested using the Zeus Scientific VZV IgM Test System and a commercially available ELISA test system. Results demonstrate that the Zeus Scientific VZV IgM ELISA Test System has comparable limits of detection to the commercially available ELISA test system.

Interfering Substances

Interfering Substances had been done based on industry standard levels of

test concentrations recommended in CLSI EP7-A2. The data is presented on the following page:

Interfering Substance Study

Zeus Scientific VZV IgM ELISA

	Spiked Level	SAMPLE 1 VZV IgM Positive	SAMPLE 1 % Positive Signal	SAMPLE 2 VZV IgM Borderline	SAMPLE 2 % Positive Signal	SAMPLE 3 VZV IgM Negative	SAMPLE 3 % Control Signal
Control-PBS	N/A	3.67		0.88		0.07	
ontrol-Ethanol	N/A	3.59		0.82		0.07	
Bilirubin	Low	3.78	103.16%	0.93	105.33%	0.08	123.53%
Bilirubin	High	3.59	97.93%	0.90	101.7%	0.06	92.65%
Albumin	Low	3.63	99.05%	0.91	103.63%	0.06	88.24%
Albumin	High	3.82	104.01%	0.89	100.45%	0.07	108.82%
IgG	Low	2.71	69.6%	0.79	83.0%	0.10	245.0%
IgG	High	1.98	48.6%	0.51	56.70%	0.16	400.0%
Cholesterol	Low	3.50	97.63%	0.88	107.6%	0.07	100.0%
Cholesterol	High	3.60	100.33%	0.88	107.6%	0.07	102.82%
Triglycerides	Low	3.80	105.94%	0.87	106.99%	0.07	100.0%
Triglycerides	High	3.79	105.61%	0.88	107.6%	0.07	92.96%
Hemoglobin	Low	3.77	102.81%	0.94	106.58%	0.14	201.47%
Hemoglobin	High	4.06	110.66%	0.97	109.64%	0.11	167.65%
Intralipid	Low	3.77	102.73%	0.87	98.53%	0.08	120.59%
Intralipid	High	3.62	98.66%	0.87	98.75%	0.07	98.53%
Control	N/A	3.66		0.89		0.06	

As depicted in the table above, the positive samples showed a range of recovery from 110.66% with the high spike of hemoglobin to a low of 48.6% with the high spike of IgG. The negative sample showed a range of recovery from 400% with the high spike of IgG to a low of 88.24% with the low spike of albumin. The borderline sample showed a range of recovery of 109.64% with the high spike of hemoglobin to a low of 83% with the low spike of IgG.

Some elevation of signal in the presence of excess hemoglobin was noted. The anti-IgG absorbent (SaVE Diluent) has been found to functionally remove $\geq$ 13.9 mg/mL IgG from human serum. Patients with an IgG level exceeding 14 mg/mL may require additional treatment to neutralize all IgG. Excessively high levels of IgG have been shown to reduce reactivity to VZV IgM antibody.

Cross-Reactivity

A minimum of 10 samples, negative for VZV IgM, were acquired and the reactivity confirmed using the predicate device. The 10 samples were subsequently tested for cross-reactivity. In all cases the specimens remained negative for VZV IgM. Please refer to the data below. **All results are presented as Index Values except where noted.**

Sample ID	EBV VCA IgM ELISA Result	Zeus Scientific VZV IgM ELISA Result
EBV M 5	3.54	0.77
EBV M 13	4.95	0.50
EBV M 15	1.94	0.40
EBV M 16	3.42	0.33
EBV M 17	5.23	0.52
EBV M 19	2.24	0.18
EBV M 20	1.19	0.10
431062	6.03	0.76
430410	3.50	0.32
430411	3.80	0.83

Sample ID	CMV IgM ELISA Result	Zeus Scientific VZV IgM ELISA Result
CMV M 33	5.22	0.66
CMV M 34	4.42	0.53
CMV M 35	1.63	0.64
CMV M 36	1.45	0.21
CMV M 37	1.57	0.26
CMV M 41	2.65	0.42
RD3901	6.92	0.89
00177	9.00	0.13
429023.00	6.34	0.86
429057.00	3.33	0.78

Sample ID	IU/mL RF IgM ELISA Result	Zeus Scientific VZV IgM ELISA Result
RF M 2	24.2	0.08
ARF 1	16.7	0.06
ARF 2	93.9	0.72
ARF 3	65.5	0.53
ARF 4	45.4	0.40
ARF 5	19.5	0.06
ARF 6	71.4	0.17
430066	85.8	0.66
430067	93.9	0.39
436932	25.6	0.21

Sample ID	Lyme IgM ELISA Result	Zeus Scientific VZV IgM ELISA Result
Lyme M 2	4.41	0.43
Lyme M 7	3.76	0.40
Lyme M 13	5.27	0.56
Lyme M 16	1.16	0.21
Lyme M 17	3.43	0.37
Lyme M 18	1.59	0.21
Lyme M 20	3.27	0.32
Lyme M 23	4.35	0.64
430068.00	2.26	0.64
436804.00	3.51	0.61

Sample ID	Mumps IgM ELISA Result	Zeus Scientific VZV IgM ELISA Result
Mumps1	5.40	0.17
Mumps2	5.30	0.14
Mumps3	4.80	0.16
Mumps4	4.40	0.13
Mumps5	2.18	0.09
Mumps6	1.48	0.08
Mumps7	4.88	0.11
Mumps8	4.17	0.13
Mumps9	3.65	0.11
Mumps10	2.81	0.10

Sample ID	Toxo IgM ELISA Result	Zeus Scientific VZV IgM ELISA Result
Toxo M 38	1.42	0.36
Toxo M 45	2.95	0.15
Toxo M 46	3.34	0.71
Toxo M 47	3.18	0.41
SX36034	1.86	0.23
RD4024	1.64	0.79
430472	1.95	0.18
434830	1.99	0.25
434831	2.06	0.21
434832	2.11	0.26

Sample ID	Measles IgM ELISA Result	Zeus Scientific VZV IgM ELISA Result
Measles1	2.49	0.31
Measles2	1.61	0.26
Measles3	1.53	0.23
Measles4	1.82	0.26
Measles5	1.32	0.24
Measles6	2.21	0.30
Measles7	1.64	0.24
Measles8	1.25	0.20
Measles9	2.14	0.30
Measles10	2.68	0.30

Sample ID	Rubella IgM ELISA Result	Zeus Scientific VZV IgM ELISA Result
RM 18	1.15	0.20
RM 19	1.51	0.33
RM 20	1.96	0.28
RM 35	1.93	0.19
RM 36	1.47	0.04
RM 37	2.55	0.08
RD3847	2.29	0.63
RD4814	2.91	0.18
437706	2.09	0.18
RD6766	2.24	0.10

Result Key:
Positive
Equivocal
Negative

IgM Destruction

A VZV IgM destruction experiment was performed to assure that the antibody which is detected by the Zeus Scientific VZV IgM ELISA Test System is indeed IgM antibody. 2% beta-mercaptoethanol was the IgM destroying agent used in this study.

The results of the VZV IgM destruction study clearly demonstrate that the IgM antibody was destroyed, capturing the information that the antibody detected by the Zeus Scientific VZV IgM ELISA Test System is indeed VZV IgM antibody.

IgG/RF Removal

The Zeus Scientific VZV IgM ELISA Test System provides sample diluent which binds IgG and RF antibodies which may potentially cross-react with IgM antibodies during assay procedure. An IgG/RF removal experiment was performed. Results presented below demonstrate that the Sample Diluent eliminates reactivity of IgG and RF.

	IgG Sample Diluent				IgM Sample Diluent			
	IgG Conj				IgG Conj			
Sample ID	OD	ISR	OD	ISR	OD	ISR	OD	ISR
VZG+ 7	2.902	8.221	0.189	0.536	0.002	0.006	0.11	0.311
VZG+ 19	>3.0	8.497	0.23	0.651	0.0	0.0	0.068	0.192
RF+ 5	0.13	0.369	0.016	0.045	0.006	0.016	0.017	0.047
VZM+ RD5161	2.914	8.254	0.776	2.197	0.0	0.001	0.728	2.063
VZM- 426642	>3.0	8.497	0.076	0.214	0.0	0.0	0.023	0.006
VZM- 418523	1.335	3.78	0.172	0.487	0.001	0.003	0.099	0.282
VZG7/RF5	2.325	6.586	0.255	0.721	0.0	0.0	0.08	0.227
VZG19/RF5	2.768	7.84	0.213	0.604	0.0	0.0	0.044	0.124

Precision

Six samples were prepared based on their activity with the Zeus Scientific VZV IgM ELISA Test System. Two samples selected were clearly negative, two were clearly positive and two were near the assay cut0off. This panel was split into six aliquots and tested at three sites. On each day of testing, each sample was diluted twice and each dilution run in quadruplicate, resulting in eight results. This was performed for three days at each facility. A summary of this testing and calculations for the mean, standard deviation and CV appear in the following tables:

Intra Assay Precision Summary:

	Site 1			Site 2			Site 3		
	Day 1	Day 2	Day 3	Day 1	Day 2	Day 3	Day 1	Day 2	Day 3
Sample 1									
mean	3.38	3.52	3.50	3.60	4.21	3.69	3.43	3.54	3.38
sd	0.10	0.06	0.08	0.03	0.12	0.06	0.08	0.10	0.07
%CV	2.8%	1.8%	2.2%	1.0%	2.9%	1.5%	2.3%	2.7%	2.1%
Sample 2									
mean	2.89	2.90	2.86	2.96	3.18	2.92	2.99	2.97	2.95
sd	0.03	0.02	0.09	0.05	0.04	0.06	0.03	0.08	0.07
%CV	1.0%	0.8%	3.0%	1.6%	1.4%	2.1%	1.1%	2.7%	2.3%
Sample 3									
mean	0.26	0.23	0.24	0.34	0.40	0.33	0.19	0.20	0.18
sd	0.01	0.01	0.01	0.01	0.01	0.01	0.01	0.01	0.01
%CV	5.0%	2.3%	3.4%	2.1%	2.9%	3.8%	3.8%	7.5%	8.0%
Sample 4									
mean	0.13	0.11	0.10	0.15	0.14	0.13	0.12	0.13	0.10
sd	0.00	0.00	0.00	0.01	0.01	0.01	0.01	0.01	0.01
%CV	3.6%	3.6%	2.6%	5.0%	4.0%	7.1%	7.5%	7.3%	8.5%
Sample 5									
mean	0.91	0.89	0.94	0.82	0.89	0.91	0.95	0.91	0.93
sd	0.01	0.02	0.02	0.02	0.01	0.02	0.02	0.03	0.02
%CV	1.5%	2.5%	2.4%	2.8%	1.5%	1.8%	2.6%	2.8%	1.7%
Sample 6									
mean	0.90	0.89	0.88	0.73	0.87	0.91	1.00	0.93	0.91
sd	0.02	0.02	0.01	0.02	0.02	0.01	0.03	0.02	0.03
%CV	3.0%	2.0%	0.9%	3.3%	2.4%	1.4%	3.3%	2.5%	3.4%

		Inter-Assay Precison Summary			Between Site
		Site 1	Site 2	Site 3	Summary
Sample 1	mean		3.84	3.45	3.6
	sd	0.10	0.29	0.10	0.3
	%CV	0.03	0.07	0.03	7.1%
Sample 2	mean	2.90	3.02	2.97	3.0
	sd	0.10	0.13	0.06	0.1
	%CV	0.02	0.04	0.02	3.4%
Sample 3	mean	0.20	0.36	0.19	0.3
	sd	0.00	0.03	0.01	0.1
	%CV	0.07	0.10	0.07	28.1%
Sample 4	mean	0.10	0.14	0.11	0.1
	sd	0.00	0.01	0.01	0.0
	%CV	0.11	0.07	0.13	14.1%
Sample 5	mean	0.90	0.87	0.93	0.9
	sd	0.00	0.05	0.03	0.0
	%CV	0.03	0.05	0.03	4.6%
Sample 6	mean	0.90	0.84	0.95	0.9
	sd	0.00	0.08	0.05	0.1
	%CV	0.02	0.10	0.05	8.0%

Performance Data

Clinical

Expected Values

Data was obtained from 302 prospective samples. Two samples were submitted with no sex designated. The data is visualized in the table below:

Age	Specimen Group	VZV IgM Positive	VZV IgM Negative	VZV IgM Equivocal	Invalid
1-9	Prospective Males	1	4		
	Prospective Females		3		
10-19	Prospective Males	1	10		
	Prospective Females		19	1	
20-29	Prospective Males		13		
	Prospective Females		85	2	
	Sex Unknown		1		
30-39	Prospective Males		14		
	Prospective Females		64		
	Sex Unknown		1		
40-49	Prospective Males		7		
	Prospective Females		26	1	
50-59	Prospective Males		7		
	Prospective Females	1	16		
60-69	Prospective Males		4		
	Prospective Females	2	10		
70+	Prospective Males		3		
	Prospective Females	1	4	1	
Total:	Prospective Males	2	62		
	Prospective Females	4	227	5	
	Sex Unknown		2		
	Total:	6	291	5	
	total	**302**			

Agreement Summary

The presence of VZV IgM antibody in 302 prospective samples and 36 retrospective samples was evaluated at three sites using the Zeus Scientific VZV IgM ELISA Test System and a commercially distributed VZV IgM ELISA test system.

Prospective Samples:Combined Sites

Commercial ELISA Results

Zeus Scientific,Inc

	+	-	+/-	Totals
+	6	4	2	12
-		281		281
+/-		7	2	9
Totals	6	292	4	302

Positive % Agreement = 6/6 = 100%
95% Confidence Interval**= 54.1% to 100.0%
Negative % Agreement = 281/294 = 95.6%
95% Confidence Interval**= 92.6% to 97.6%

Prospective and Retrospective Samples:Combined Sites

Commercial ELISA Results

Zeus Scientific,Inc

	+	-	+/-	Totals
+	38	4	4	46
-		282		282
+/-	1	7	2	10
Totals	39	293	6	338

Positive % Agreement = 38/39 = 97.4%
95% Confidence Interval**= 86.5% to 99.9%
Negative % Agreement = 282/297 = 95.6%
95% Confidence Interval**= 91.8% to 97.1%

The test is for *in vitro* use only.
The performance of this assay has not been established for neonatal, immunocomprimised populations, cord blood or pre-transplant patients. The use of whole blood or plasma is not established.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUL - 5 2007

Ewa K. Nadolczak
Manager Clinical Affairs
ZEUS Scientific, Inc.
P.O. Box 38
Raritan, New Jersey 08869

Re: k070317
Trade/Device Name: Zeus Scientific, VZV IgM ELISA Test System

Regulation Number: 21 CFR 866.3900
Regulation Name: Varicella-Zoster virus Serological Reagents
Regulatory Class: Class II
Product Code: LFY
Dated: January 21, 2007
Received: February 6, 2007

Dear Ms. Nadolczak:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

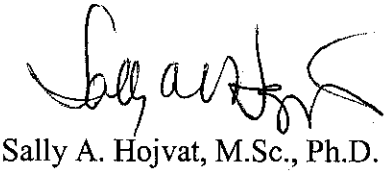
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other

Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,



Sally A. Hojvat, M.Sc., Ph.D.
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Evaluation and Safety
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Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): k 070317

Device Name: Zeus Scientific Varicella Zoster Virus IgM ELISA Test System

Indications For Use:

The Zeus Scientific Varicella Zoster Virus (VZV) IgM ELISA Test System is intended for the qualitative detection of IgM class antibodies to Varicella Zoster Virus in human serum as an aid in the diagnosis of primary infection or reactivation.

The assay performance in detecting antibodies to VZV in individuals vaccinated with the FDA licensed VZV vaccine is unknown.
The user of this assay is responsible for establishing the performance characteristics with VZV vaccinated individuals.
The assay performance in detecting antibodies to VZV in cord blood and neonates has not been established.

Prescription Use __X__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Uwe Scherf

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) k070317